



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

AUG 18 1998

Ms. Cecile Kehoe
Regulatory Manager
GumTech International, Inc.
246 East Watkins Street
Phoenix, Arizona 85004

1841 '98 AUG 21 12:45

Dear Ms. Kehoe:

This is in response to your letter of August 7, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that GumTech International, Inc. is making the following statements, among others, for the product "DentaHealth Supplement Gum:"

"Fights plaque between brushing"

"...formulated with Microdent, which studies have shown fights plaque between brushings."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, mitigate, or cure diseases, namely, plaque formation. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also indicates that, for the product DentaHealth Supplement Gum, you are making the claim "Contains Xylitol which may reduce the risk of tooth decay." This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but is a health claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between dietary sugar alcohols and dental caries (see 21 CFR 101.80). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between dietary sugar alcohols and dental caries. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.81 would misbrand the food or

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dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.80 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, dental caries.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file, OSN#60633)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-456:rjm:8/17/98:docname:60633.adv:disc31



August 7, 1998



246
East
Watkins
Street
Phoenix
Arizona
85004

Dr. Carolyn Miles
Special Nutritionals
Center for Food Safety & Applied
Nutrition
FDA
200 C St. S.W.
Washington, D.C. 20204

Dear Dr. Miles:

This is a 30-day notification for a dietary supplement
chewing gum which will be on the market within 30 days. The
product name is No Smoke Zone™ Supplement Gum. The claims on
the label are:

When smoking is not an option

- Helps combat irritability
- Helps reduce teeth staining
- Replaces lost vitamins

The ingredients are: Vitamin C, Vitamin E, Thiamin,
Riboflavin, Vitamin B6, B12, Grape Seed Extract, Green Tea
Powder, Mate Powder, Microdent (proprietary blend of
polydimethylsiloxane and a nonionic surfactant), Plantain
Powder, St. John's Wort, Skullcap Powder, Valerian Root Powder.

Corporate
800
676
4769

Sincerely,

Cecile Kehoe/Regulatory Manager

Cecile Kehoe

60633



August 7, 1998

RECEIVED
8/11/98

246
East
Watkins
Street
Phoenix
Arizona
85004

Dr. Carolyn Miles
Special Nutritionals
Center for Food Safety & Applied
Nutrition
FDA
200 C St. S.W.
Washington, D.C. 20204

Dear Dr. Miles:

This is a 30-day notification for a dietary supplement
chewing gum which will be on the market within 30 days. The
product name is **DentaHealth™ Supplement Gum**. The claims on the
label are:

- Fights plaque between brushing
- Helps keep your teeth and gums clean and healthy
- Freshens your breath
- DentaHealth™ Gum is formulated with **Microdent™**, which
studies have shown fights plaque between brushings.
- Contains **Xylitol** which may reduce the risk of tooth
decay; **Baking Soda** and **Chlorophyll** to sweeten breath and absorb
odor; **Aloe Vera**, **CoQ10**, and **Vitamin E** for healthy gums;
Dicalcium Phosphate for healthy teeth and **Menthol Crystals** for
breath freshening.

Corporate
800
676
4769

Sincerely,

Cecile Kehoe/Regulatory Manager

Cecile Kehoe

see also docket 97S-0163

60633
